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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,225	02/28/2006	Henry M. Grage Jr	2G0211511	7570

23506 7590 05/12/2008

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EXAMINER	
TANNER, JOCELIN C	

ART UNIT	PAPER NUMBER
4133	

MAIL DATE	DELIVERY MODE
05/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/570,225	GRAGE JR ET AL.	
	Examiner	Art Unit	
	JOCELIN C. TANNER	4133	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/21/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is in response to the application filed on February 28, 2006 in which claims 1-20 are presented for examination.

Status of Claims

Claims 1-20 are pending, of which 1, 9, 10, 18 and 19 are in independent form. Claims 1-4, 6, 10-13, and 15 are rejected under 35 U.S.C. 102(b) and claims 5, 7, 8, 9, 14, and 16-20 are rejected under 35 U.S.C. 103(a).

Information Disclosure Statement

The information disclosure statement (IDS) submitted on September 21, 2006 was filed after the mailing date of the patent application on February 28, 2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 5 and 14, the limitation, "helical spiral

array" renders the claim and vague and indefinite because it isn't clear what the axis of the helical spiral array is. Appropriate correction is required.

Claim Rejections - 35 USC § 102

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-4, 6, 10-13, 15 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Verdonk et al (US Patent No. 6,306,152).

Regarding independent claim 1, Verdonk et al or “Verdonk” herein, discloses a lancing device for collecting a sample of body fluid from a sampling site on the skin of a subject (column 4, lines 13-14), a lancing device including an outer body housing and a lancet (FIG. 3, element #104), the lancet being movable between a first position within the end cap or “outer body housing” (FIG. 3, element #110) and a second position wherein at least a sharp tip portion of the lancet extends through an opening (column 4, lines 56-59 and FIG. 3, element #134) in the outer body housing, the lancing device further including lips or “contact face” (FIG. 3, element #136) surrounding the opening and a plurality of legs or “ribs” (FIG. 9, element #200) projecting from the contact face in a ring-shaped pattern (column 5, lines 24-25), wherein each plurality of ribs has a first end adjacent the opening and extending length-wise away from the opening and across the contact face (FIG. 9).

3. Regarding claim 2, Verdonk discloses a plurality of legs or "ribs" projecting from the lips or "contact face" in a regularly spaced array (FIG. 9, element #200) wherein the skin stabilizers are arranged in a desired order.

4. Regarding claim 3, Verdonk discloses legs or "ribs" that are spaced about the opening in a circular array (FIG. 9, element #200) wherein the plurality of ribs are placed around the opening of the contact face.

5. Regarding claim 4, Verdonk discloses legs or "ribs" that are spaced about the opening in a radial array (FIG. 9, element #200) wherein each of the legs or "ribs" are arranged from the center outward along different radii.

6. Regarding claim 6, Verdonk discloses legs or "ribs" that are spaced about the opening in an annular circumferential array wherein the plurality of legs are arranged in the form of a ring around the opening and within the circumference of the contact face (column 5, lines 24-26).

7. Regarding independent claim 10, Verdonk discloses an endcap for a lancing device, an endcap (FIG. 3, element #110) including a first end for connection to the lancing device, and a second end defining an opening (FIG. 3, element #134) through which a sharp tip of a lancet can pass, the second end further comprising a contact face surrounding the opening and at least a plurality of legs or "ribs" (FIG. 3, element #200)

projecting from the contact face in a ring-shaped pattern (column 5, lines 24-25), wherein each plurality of ribs has a first end adjacent the opening and extending length-wise away from the opening and across the contact face (FIG. 9).

8. Regarding claim 11, Verdonk discloses an endcap having a plurality of legs or "ribs" projecting from the contact face in a regularly spaced array (FIG. 9, element #200) wherein the skin stabilizers are arranged in a desired order.

9. Regarding claim 12, Verdonk discloses legs or "ribs" that are spaced about the opening in a circular array (FIG. 9, element #200) wherein the plurality of legs or "ribs" are placed around the opening of the contact face.

10. Regarding claim 13, Verdonk discloses legs or "ribs" that are spaced about the opening in a radial array (FIG. 9, element #200) wherein each of the ribs are arranged from the center outward along different radii of the circular contact face.

11. Regarding claim 15, Verdonk discloses legs or "ribs" that are spaced about the opening in an annular circumferential array wherein the plurality of ribs are arranged in the form of a ring within the circumference of the contact face (column 5, lines 24-26).

12. Regarding independent claim 19, Verdonk discloses a method of collecting a sample of body fluid using a lancing device, including:

lancing the skin of a subject at a lancing site (column 5, lines 48-50); and compressing a ribbed contact face of the lancing device against the skin adjacent the lancing site (column 5, lines 42-47), a ribbed contact face including a plurality of ribs extending length-wise from an outer edge of the contact face inwardly (FIG. 9, element #200) toward an expression zone or lancing site.

The methods steps of claim 19 are inherently performed when the verdonk device is used to lance skin for blood sampling.

13. Claims 9 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Davison (WO 01/62150 A1).

Regarding independent claim 9, Davison discloses a skin pricker or "lancing device" (column 1, lines 13-15) for collecting a sample of body fluid from a sampling site on the skin of a subject, a lancing device including an outer body housing and a lancet, the lancet being movable between a first position within the outer body housing and a second position wherein at least a sharp tip portion of the lancet extends through an opening in the outer body housing (column 1, lines 15-21), the lancing device further including a contact face surrounding the opening (column 2, lines 11-12, FIG. 1, element #2) and a plurality of studs or recessed hemispherical dimples on the contact face (column 2, lines 14-16, FIG. 1, element #4).

14. Regarding independent claim 18, Davison discloses an endcap for a lancing device, a nose cone or "endcap" (FIG. 1, element #1) including a first end for connection

to the lancing device, and a second end defining an opening through which a sharp tip of a lancet can pass (column 2, lines 13-14), the second end further including a contact face surrounding the opening (column 2, lines 11-12, FIG. 1, element #2) and a plurality of studs or recessed hemispherical dimples on the contact face (column 2, lines 14-16, FIG. 1, element #4).

15. In light of the rejections under 35 U.S.C. 112 second paragraph above and as best understood by the examiner, Claims 5, 7, 8, 14, 16, 17 and 20 are rejected under 35 U.S.C. 103(a) below.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 5, 7, 8, 14, 16, 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verdonk et al (US Patent No. 6,306,152) in view of Moerman (6,706,049).

Regarding claims 5 and 14, Verdonk discloses all of the limitations previously discussed except for a helical spiral array arrangement of ribs about the opening in the contact face or surface of the endcap of the lancing device.

Moerman teaches a contact ring or endcap for a lancing device having a non-planar, multi-contoured surface, wherein the surface features or ribs are linear, stepped or curved (column 5, lines 26-29 and 36-40).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected a linear, stepped or curved shape for the surface features in the device of the combination of Verdonk and Moerman, since these shapes are known options for surface features on the endcap of a lancing device and a person of ordinary skill has good reason to pursue the known options within his or her technical grasp with a reasonable expectation of success, i.e. better contact of the lancing device with the skin. The Examiner notes that each curved surface feature arranged in a radial array in the device of the combination of Verdonk and Moerman, forms a part of a helix. Thus, the curved surface features in the device of the combination of Verdonk and Moerman are arranged in a helical spiral array.

18. Regarding claims 7, 8, 16 and 17, Verdonk discloses all of the limitations that have been previously discussed except for: (i) a convex contact face; and (ii) a concave contact face. Moerman teaches a contact face for an endcap of a lancing device having outer and inner radial portions wherein the outer and the inner radial portions can be linear, convex or concave (column 5, lines 41-45).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected a linear, convex or concave shape for the contact face in the device of the combination of Verdonk and Moerman, since these

shapes are known options for a contact face of a lancing device and a person of ordinary skill has good reason to pursue the known options within his or her technical grasp with a reasonable expectation of success, i.e. better contact of the lancing device with the skin.

19. Regarding claim 20, the Verdonk discloses all elements that have been previously discussed in claim 19 except for twisting the ribbed contact face in contact with the skin.

Moerman teaches wherein the contact ring or contact face is squeezed into contact with the outer radial portion and the inner radial portion by squeezing or "twisting" the ribbed contact face (column 7, lines 8-10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have placed the device of Verdonk into contact with skin by twisting the device, as taught by Moerman, to maximize the expression of blood flow from the lancing site.

The methods steps of claim 20 are rendered obvious by the above discussion.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sharma et al (US Patent No. 6,491,709) is related to lancing devices for blood collection from alternate sites.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frantz Coby can be reached on 571-272-4017. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/ 5/01/2008
Examiner, Art Unit 4133

/Frantz Coby/
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